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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,560	02/09/2001	Marianne Harboe	58982.000002	6162

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/779,560	HARBOE, MARIANNE	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6,9-14,16-18,29-31,35,36,39,42 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6,9-14,16-18,29-31,35,36,39,42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/13/2006 has been entered.

[2] Claims 5-6, 9-14, 16-18, 29-31, 35-36, 39, and 42-43 are pending in the application.

[3] Applicant's amendment to the claims, filed on 3/13/2006, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[4] Applicant's arguments filed on 3/13/2006 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, First Paragraph

[6] Claims 5-6, 9-14, 16-18, 29-31, 35-36, 39, and 42-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 9 (claims 5-6, 10, 11-14, 16-18, 35-36, and 42-43 dependent therefrom) is drawn to a method using a medium that comprises chymosin activity and glucoamylase activity derived from the cultivation of an organism selected from a bacterial species, a yeast species, or a species of filamentous fungi. Claims 29-31 and 39 limit the organism to comprising a gene encoding the chymosin activity, wherein the gene is "derived from" a mammalian species as encompassed by the claims.

The specification discloses that the claimed method can be applied to "a medium that is derived from the cultivation of a recombinant microorganism that has an inserted gene expressing the aspartic protease" (paragraph bridging pp. 7-8), that the claimed method is applicable to "preparations of aspartic proteases derived from naturally produced aspartic protease by addition or deletion of one or more amino acids or substituting one or more amino acids herein" (specification at p. 8, lines 32-35) and states that the term "aspartic protease" includes pro-chymosin and chymosin (p. 8, line 24). Thus, in accordance with MPEP § 2111.01, which directs the examiner to interpret claims as broadly as their terms allow, the examiner has interpreted "chymosin activity" in claim 9 as encompassing *any* chymosin from any source, including any mutant of chymosin or in claims 29-30 and 39 as encompassing *any* chymosin from the recited mammalian sources, including any mutant thereof having any structure that maintains at

least 75% chymosin activity at pH 1.0 to 1.99. Also, regarding claims 29-31 and 39, which limit the organism to comprising a "gene encoding the chymosin activity," it is noted that the term "gene" has been interpreted as encompassing naturally occurring regulatory elements and untranslated regions necessary for expression (see the "Revised Interim Written Description Guidelines Training Materials," Example 6).

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species of the claimed or recited genus of chymosin polypeptides and genes encoding therefore, i.e., bovine chymosin. Other than this single species, the specification fails to disclose other representative species of the genus of recited chymosins and genes encoding therefore. In the case, the genus of chymosins and genes encoding therefore encompasses widely variant species, including any polypeptide having any structure with chymosin activity and any

gene encoding therefor or any naturally occurring gene encoding a chymosin from any mammalian source as encompassed by the claims. The disclosure of the single representative species as noted above fails to reflect the variation among the members of the genus.

Therefore, given the lack of description of a representative number of compounds, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

It is noted that a similar rejection has been previously raised (¶ [9] pp. 5-8 of the 3/18/2005 Office action) and subsequently withdrawn with respect to currently pending claims 5-6, 10-14, 16-18, 35-36, and 42-43 in the 9/12/2005 Office action. However, upon further consideration, the examiner notes that withdrawal of the rejection appears to be premature and has reinstated the rejection for the reasons noted above. Applicant traverses the previous written description rejection as set forth in the 3/18/2005 Office action by arguing that the genus of media comprising chymosin and glucoamylase activities is adequately described, pointing to disclosed species of such media (pp. 5-7 of the response filed on 6/21/2005). However, while the specification discloses several species of media comprising chymosin and glucoamylase activities, these media all appear to comprise bovine chymosin, which fails to support the recited genus of chymosin polypeptides and genes encoding therefor as encompassed by the claims.

[7] Claim(s) 5-6, 9-14, 16-18, 29-31, 35-36, 39, and 42-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method using a medium having chymosin and glucoamylase activities as disclosed in the specification at pp. 9-16, Examples 1-3, does not reasonably provide enablement for all media comprising chymosin and glucoamylase activities as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

The breadth of the claims: Claim 9 (claims 5-6, 10, 11-14, 16-18, 35-36, and 42-43 dependent therefrom) is drawn to a method using a medium that comprises chymosin activity and glucoamylase activity derived from the cultivation of an organism selected

from a bacterial species, a yeast species, or a species of filamentous fungi. Claims 29-31 and 39 limit the organism to comprising a gene encoding the chymosin activity, wherein the gene is "derived from" a mammalian species as encompassed by the claims. The specification discloses that the claimed method can be applied to "a medium that is derived from the cultivation of a recombinant microorganism that has an inserted gene expressing the aspartic protease" (paragraph bridging pp. 7-8), that the claimed method is applicable to "preparations of aspartic proteases derived from naturally produced aspartic protease by addition or deletion of one or more amino acids or substituting one or more amino acids herein" (specification at p. 8, lines 32-35) and states that the term "aspartic protease" includes pro-chymosin and chymosin (p. 8, line 24). Thus, in accordance with MPEP § 2111.01, which directs the examiner to interpret claims as broadly as their terms allow, the examiner has interpreted "chymosin activity" in claim 9 as encompassing *any* chymosin from any source, including any mutant of chymosin or in claims 29-30 and 39 as encompassing *any* chymosin from the recited mammalian sources, including any mutant thereof having any structure that maintains at least 75% chymosin activity at pH 1.0 to 1.99. Also, regarding claims 29-31 and 39, which limit the organism to comprising a "gene encoding the chymosin activity," it is noted that the term "gene" has been interpreted as encompassing naturally occurring regulatory elements and untranslated regions necessary for expression.

The state of the prior art; The level of one of ordinary skill; The level of predictability in the art: The nucleotide sequence of an encoding nucleic acid determines the corresponding encoded protein's structural and functional properties. Predictability of

which changes can be tolerated in an encoded protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e., expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The positions within an encoding nucleic acid's sequence where modifications can be made with a reasonable expectation of success in obtaining an encoded polypeptide having the desired activity/utility are limited in any protein and the result of such modifications is highly unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. The state of the art provides evidence for the high level of unpredictability in altering a polynucleotide sequence with an expectation that the encoded polypeptide will maintain the desired activity/utility. The reference of Branden et al. ("Introduction to Protein Structure", Garland Publishing Inc., New York, 1991; cited in the Office action mailed on 3/18/2005) teaches "[p]rotein engineers frequently have been surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes" and "[t]he often surprising results of such experiments reveal how little we know about the rules of protein stability... ...they also serve to emphasize how difficult it is to design *de novo* stable proteins with specific functions" (page 247). See also the teachings of Witkowski et al. (*Biochemistry* 38:11643-11650; cited in the 3/18/2005 Office action), which support the reference of Branden et al.

The amount of direction provided by the inventor; The existence of working examples: The specification discloses only a single working example of a chymosin polypeptide, i.e., bovine chymosin. Other than this single working example, the specification fails to provide the necessary specific guidance for making the entire scope of chymosin polypeptides and genes encoding therefor as encompassed by the claims, including guidance regarding isolation of those chymosin encoding genes that have yet to be isolated from any source as encompassed by the claims and guidance regarding modification of any chymosin by substitution, addition, insertion, and/or deletion with an expectation of maintaining the desired chymosin activity.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure: While methods of isolating homologues or making variants of a given polypeptide were known in the art at the time of the invention, e.g., hybridization or mutagenesis, it was not routine in the art to screen for all genes as encompassed by the claims or all chymosin variants having a substantial number of substitutions or modifications as encompassed by the instant claims.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability, and the significant amount of non-routine experimentation required, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. As such, applicant has not provided sufficient guidance to enable one

of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

It is noted that a similar rejection has been previously raised (¶ [10] pp. 8-15 of the 3/18/2005 Office action) and subsequently withdrawn with respect to currently pending claims 5-6, 10-14, 16-18, 35-36, and 42-43 in the 9/12/2005 Office action. However, upon further consideration, the examiner notes that withdrawal of the rejection appears to be premature and has reinstated the rejection for the reasons noted above. Applicant traverses the previous scope of enablement rejection as set forth in the 3/18/2005 Office action by arguing that the evidence of enablement, namely the working examples, has been completely ignored and must be withdrawn (pp. 7-8 of the response filed on 6/21/2005). However, while the examiner does not dispute the specification's disclosure of working examples of media comprising bovine chymosin, these working examples fail to provide the necessary guidance for isolating any chymosin gene as encompassed by the claims and altering the sequence of any chymosin polypeptide with an expectation of maintaining chymosin activity for the reasons stated above.

Claim Rejections - 35 USC § 103

[8] The rejection of claim(s) 5-6, 9, 12-14, 16-18, and 42-43 under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Larsen et al. is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a previous Office action. In view of the amendment to claim 29 to limit the organism to comprising a gene encoding the chymosin activity, claims 29-31 are included in the instant rejection. The Ward et al. reference teaches the chymosin moiety of the chymosin-glucoamylase fusion protein is bovine chymosin (p. 435, right column, middle). Thus, claims 5-6, 9, 12-14, 16-18, 29-31, and 42-43 are rejected herein.

RESPONSE TO ARGUMENT: According to applicant, the teachings of Ward et al. and Larsen et al. "suggest that the pH of 2.0 is the optimal pH value for the combined activation and purification of chymosin, and there is therefore no motivation to use a pH of 2.0 as it will result in lower recovery and be more expensive." Applicant points to MPEP § 2145.X.D.1-3, discussing how proceeding against common wisdom is evidence of non-obviousness. Applicant also argues the teachings of Larsen et al. are directed to purification of chymosin from calf stomach tissue, while the instant claims require cultivation of a microorganism and fails to discuss glucoamylase activity or a reduction in its activity as encompassed by the claims. Applicant further argues the rejection has ignored the unexpected reduction in glucoamylase activity of the claimed method and that instead of achieving a reduction in glucoamylase activity, one of ordinary skill in the art would only expect to reduce chymosin activity by lowering the pH below 2.0 and not a concomitant reduction in glucoamylase activity.

Applicants' argument is not found persuasive. In response to applicant's statement that the teachings of Ward et al. and Larsen suggest the optimal pH for activation of chymosin is 2.0, while the reference of Ward et al. teaches that a pH of 2.0 is *sufficient* for chymosin activation and the reference of Larsen et al. teaches a pH of *about* 2.0 is optimal for chymosin absorption to a cation exchange matrix, nowhere do the references of Ward et al. and Larsen et al., alone or in combination, teach the optimum pH for *activation* of chymosin is 2.0. There is no evidence of record that activation of chymosin at a pH lower than 2.0 would "result in lower recovery and be more expensive" as asserted by applicant. As noted in a prior Office action, the use of pH 2.0 by Ward et al. to activate chymosin is an established pH for chymosin activation and its continued use appears to be based on the ability to compare the results of chymosin activation in one study with those of others (¶ bridging pp. 18-19 of the 3/18/2005 Office action). For example, as early as 1969, Foltmann (*Biochem J* 115:3P-4P, 1969) discloses that [c]hromatographically purified preparations of prochymosin are activated very rapidly at pH 2" (p. 4P, left column, top). In fact, Foltmann disclose that "[t]he lower the pH the higher is the initial rate of reaction" of chymosin activation (p. 3P, right column, bottom). And while Larsen et al. suggests that a pH of "about 2.0" is optimal for chymosin absorption to a cation exchange material, absorption and activation are non-analogous processes. Here, it appears that applicant has asserted a conclusion that is not supported by the cited references. If applicant maintains such a conclusion, applicant is requested to provide objective evidence supporting a conclusion that activation of chymosin is optimal at pH 2.0.

The relevant teaching of Larsen et al. is that chymosin is activatable at a pH as low as 0.5, which is undisputed by applicant and there is no evidence of record that activation of chymosin at a pH as low as 0.5 has any deleterious effect on chymosin activity. MPEP § 2144.05 states that the determination of a workable range by routine experimentation is not inventive and MPEP § 2144.06 recognizes equivalence for the same purpose as a rationale for motivation in an obviousness rejection. The use of a pH as low as 0.5 to activate chymosin as taught by Larsen et al. is a workable range for chymosin activation and is an art-recognized equivalent to activating chymosin at a pH of 2.0. According to MPEP § 2144.06, an express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. Thus, one of ordinary skill in the art would have been motivated to activate chymosin at a pH of as low as 0.5, *e.g.,* pH 1.99, in the method of Ward et al. because a pH of as low as 0.5 is an art-recognized equivalent of activating chymosin at a pH of 2.0. Applicant points to p. 435, left column, of Ward et al. as disclosing a "two step process with different pH optima" for converting prochymosin to active chymosin and asserts that lowering the pH lower than 2.0 goes against "common wisdom." However, applicant's cited teachings do not teach a two-step conversion process, but instead discuss how chymosin is activated at pH 2.0 OR pH 4.5. There is no teaching at p. 435, left column that would suggest raising the pH from 2.0 to 4.5. Instead, Ward et al. recognizes that pH 2.0 is sufficient for processing of the fusion protein without need of raising the pH following pH 2.0 treatment (p. 439, right column, top).

In response to applicant's argument that the rejection ignores the alleged unexpected results of the claimed method, the examiner has previously addressed this issue in previous Office actions. As noted in previous Office actions, the disclosure teaches that treatment at the recited pH range for a time of 0.1 minutes to 48 hours will achieve the recited level of deactivated glucoamylase, while maintaining the desired level of chymosin activity. It is acknowledged that neither Ward nor Larsen teaches treating the respective medium at low pH specifically for reducing glucoamylase activity. However, the examiner maintains the position that by practicing the method of Ward at a lower pH, *e.g.,* pH 1.99, one would inherently achieve the recited reduction in glucoamylase activity, while maintaining the desired level of chymosin activity. The reference of Ward teaches treating the medium comprising chymosin and glucoamylase activities for 30 minutes, a period of time that falls within the disclosed 0.1 minute to 48 hour time period. In view of the disclosure, it necessarily flows that treatment of the medium at a pH as low as 0.5 for 30 minutes would achieve the recited level of deactivated glucoamylase, while maintaining the desired level of chymosin activity.

In this case there is no evidence of record that the use of pH 1.99 provides any marked improvement in glucoamylase inactivation over pH 2.0. Using a rough approximation of the data presented in the specification, it is the examiner's position that the desired reduction in glucoamylase activity, while maintaining the desired level of chymosin activity is achieved using the method of Ward. Example 2 of the instant specification teaches that the medium of *Aspergillus niger* var. *awamori* transformed with a plasmid encoding a glucoamylase-chymosin fusion protein cultured at a pH of 5.6

had glucoamylase activity of 30,619 U/mL and at pH 1.8 had glucoamylase activity of 4,020 U/mL (p. 13, top). Figure 1 of the specification shows that the remaining glucoamylase activities following treatment of a medium comprising a glucoamylase-chymosin fusion protein at pH 1.8 and 2.0 are substantially similar. Thus, by extrapolation of the results of Example 2 and Figure 1 as described above, one would reasonably expect that the remaining glucoamylase activity of the medium as described in Example 2 treated at pH 2.0 would be substantially similar to the glucoamylase activity of 4,020 U/mL at pH 1.8. One of ordinary skill in the art would recognize that one practicing the method of Ward would achieve similar reduction in glucoamylase activity to the recited level. Thus, the evidence relied upon fails to establish that the differences in glucoamylase inactivation are unexpected.

Also, it is noted that applicants' specification asserts that a time period of as little as 0.1 minute at a pH lowered to, *e.g.,* 1.99, is sufficient to achieve the recited reduction in glucoamylase activity while maintaining the recited level of chymosin activity (p. 7, middle). Also, dependent claim 18 limits the time period to as little as 0.1 minutes at a pH of 1.99. The method of Ward teaches treating the medium at a pH of 2 for 30 minutes, which is a significantly longer time period than the 0.1 minute time range disclosed in the specification. The results of Figure 1 of the specification show that the difference in reduction of glucoamylase activity at pH 1.99 and pH 2 is negligible. Thus, one of ordinary skill in the art would expect that by lowering the pH of a medium from 5 to 2 and maintaining the pH at 2 for a time of 30 minutes would achieve a nearly identical reduction in glucoamylase activity by lowering the pH of a medium from 5 to

1.99 for a time period greater than 0.1 minute, which according to the disclosure, would achieve inactivation of at least 50% of the glucoamylase activity.

Further, Ward provides evidence that at least 85% chymosin activity is maintained by lowering the pH to 2 by teaching that, by lowering the pH of the medium from 5 to 2 increased chymosin activity by 5-fold (p. 438, left column, bottom).

At least for the reasons stated above, one of ordinary skill in the art would have recognized that the use of the recited pH range in the method of Ward et al. is obvious in view of the prior art, all limitations of the claims are expressly or inherently taught by the cited references, the inherent characteristic necessarily flows from the prior art teachings, and the alleged unexpected results are not so unexpected.

Conclusion

[9] Status of the claims:

- Claims 5-6, 9-14, 16-18, 29-31, 35-36, 39, and 42-43 are pending.
- Claims 5-6, 9-14, 16-18, 29-31, 35-36, 39, and 42-43 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656